

REMARKS

The present communication is responsive to the Office Action mailed July 27, 2006. A petition for a one-month extension of the term for response to said Office Action, to and including November 27, 2006, is transmitted herewith. Applicants also submit herewith a Request For Continued Examination.

By way of this Request for Continued Examination, Applicants have now introduced new claims 39 and 40, support for which is contained throughout the specification, e.g., Examples 1 and 7, respectively. In addition, Applicants have amended claims 24 and 25 herein in order to correct a typographical error. Accordingly, no new matter has been added.

In response to the rejection of claims 16-38 under 35 U.S.C. §103, Applicants reiterate their arguments of record. With respect to the newly added claims, there is no teaching or suggestion in the cited references, taken individually or collectively, that the solubility of hydrocortisone (or a derivative thereof) is greater in pentylene glycol than in hexylene glycol, butylene glycol, and propylene glycol, or that the bioavailability of hydrocortisone is enhanced in pentylene glycol.

The Office Action repeats the prior position of the Patent Office in that the Fares Declaration was not convincing. In the Examiner's view, while setting forth the reasoning as to why the applicant chose to use pentylene glycol, and the effects noticed with the concurrent use of pentylene glycol with hydrocortisone, the Declaration did not set forth any argument as to why the pentylene glycol/hydrocortisone combination is patentable.

Applicants are not aware of any rule or provision in the MPEP that requires a declarant to provide an "argument" in favor of patentability. In any event, Applicants' arguments in

favor of patentability are explicitly set forth in the prior responses. Contrary to the allegations in the Office action, however, Dr. Fares does in fact explain why he believes the claimed invention is patentable and he reiterates Applicants' position that the claimed invention achieves results that would not have been expected in view of the collective teachings of the cited prior art. These results, which flow from the unexpected discovery the hydrocortisone is more soluble in pentylene glycol than in other diols disclosed in the cited prior art, include greater aesthetic appeal, less tackiness and greater penetration and bioavailability.

The actual evidence that establishes unexpected results is set forth in the specification. The record does not reflect that this evidence has been considered in the obviousness determination. On the other hand, the MPEP is explicit as to how such evidence is to be treated. Objective evidence of secondary considerations, e.g., unexpected results, is relevant to the issue of obviousness, and regardless of whether it is presented in the specification, by counsel or via affidavit or declaration, it must be considered in every case in which it is present, and that when evidence of any such secondary consideration is submitted, the examiner must evaluate the evidence. See, MPEP §2141(Rev. 3, August 2005 at 2100-125 and 158) (citing *In re Soni*, 34 U.S.P.Q.2d 1684, 1687 (Fed. Cir. 1996) (error not to consider evidence presented in the specification)). Accordingly, Applicants once again request consideration of the evidence along with this response.

As described in the present specification, the claimed invention achieves several unexpected results. These results flow from Applicants' discovery that hydrocortisone and its derivatives are more soluble in pentylene glycol than other polyols such as glycerol, propylene glycol, butylene glycol and hexylene glycol, which are the glycols taught in Quigley and

Cooper. More specifically, as shown in Example 1 on page 11, Applicants discovered that hydrocortisone is about two times more soluble in pentylene glycol than in hexylene glycol, about 1.5 times more soluble in pentylene glycol than in propylene glycol, and about 1.25 times more soluble in pentylene glycol than in butylene glycol. There are no teachings or suggestions in Quigley or Cooper to these effects. As taught in the present specification, there are at least three unexpected benefits that flow from the combination of pentylene glycol and hydrocortisone and its derivatives, namely aesthetic appeal, less tackiness and greater bioavailability. The first two advantages are described on pages 5-6 as follows:

Due to the greater solubility of the active agents in pentylene glycol, the amounts of the other solvents are significantly lower, e.g., about 20 to 95 percent less than if pentylene glycol were not present. Relatively high amounts of glycols are undesirable from several standpoints, especially in terms of aesthetic appeal and tackiness. In contrast, compositions of the present invention are more aesthetically acceptable and have less tackiness.

In Example 7 on pages 16-18 of the specification, Applicants compared the rate of release of hydrocortisone from various commercially available one percent hydrocortisone anti-itch creams and ointments. The results show that the release rate of hydrocortisone from a gel of the present invention was about 100 times greater than the commercial products, none of which contains pentylene glycol. As described in paragraph 34 on page 18, and illustrated in Fig. 1, the results also show that the compositions of the present invention provided greater availability of the active agent to penetrate the affected area on the skin or scalp, and thus provided greater bioavailability of the active agent.

As attested to by Dr. Fares, these results would not have been expected based on the collective teachings of the prior art. By specifically limiting the diols to C3, C4 and/or C6 diols, Cooper and Quigley are believed to teach away from the claimed invention. Vollhardt's primary objective was to increase water resistance or in other words, the amount of time that a sunscreen agent actually stays on the surface of the skin. Vollhardt does teach that his invention can also be practiced with antioxidants, anti-inflammatory compounds, anti-microbial compounds, antiperspirants, fragrances and skin whitening compounds. See columns 4-5. Hydrocortisone is thus merely one of many, many other of Vollhardt's less preferred active agents, leaving one skilled in the art to pick and choose from a myriad of combinations in order to arrive at the presently claimed invention.

In view of the foregoing, applicants respectfully request reconsideration of the presently claimed invention, including newly added claims 39 and 40, in view of the evidence contained in the specification, as elaborated upon in the Fares Declaration. Applicants submit that the presently claimed invention defines a patentable contribution to the art. Accordingly, reconsideration and withdrawal of the rejection, and allowance of claims 16-40, are respectfully requested.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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